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10/580,164	05/18/2006	Mark Ian Christie	07-1009-W0-US	7952

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,164	CHRISTIE ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-12,14-16,18 and 19* is/are pending in the application.

4a) Of the above claim(s) *12 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,11,14-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-9 have been canceled previously and claims 13, 17 have been canceled in the amendment filed 5/28/2008). Amended claims 10, 14-16, 19 (5/28/2008) and original claim 11 are under consideration. Claims 12and 18 are withdrawn from consideration by the Examiner as drawn to non-elected claims.

2. Receipt of Applicant's arguments and amendments filed on 5/28/2008 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 5/28/08:

(i) the rejection of claims 10-11, 13-17, 19, under 35 USC 112, second paragraph.

Applicant's arguments with respect to claims 10-11, 14-16, 19 have been considered but are moot in view of the new ground(s) of rejection over claims 10-11, 14-16, 19.

4. Applicant's arguments filed on 5/28/2008 have been fully considered but were persuasive in part. The issue remaining and new issue are stated below.

Claim rejections-35 USC § 112, scope of enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 10-11, 14-16, 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, does not reasonably provide enablement for a method for treating MS comprising administering a therapeutically effective amount of an inhibitor of IL-17 activity to a patient in need thereof as recited in claim 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 2-7 of the previous Office action (1/28/2008).

Applicants argue that claim 10, the only pending independent claim, has been amended to delete the language cited in the rejection and to recite treatment of MS by administering a therapeutically effective amount of an anti-IL-17 antibody or anti-IL-17 antibody fragment and therefore, Applicants submit that the specification enables the amended claims. Applicants also argue that anti-IL-17 antibodies and antibody fragments as now specifically recited in claim 10 are well known in the art, such as the references cited in the present specification, at e.g., page 1, line 22; page 8, line 25 - page 9, line 3; page 13, lines 4-7 and that the specification is also replete with other references in the literature that disclose how one skilled in the art would practice various aspects of the invention, e.g., library methods for obtaining candidate agents, page 5, lines 4-18; generation of antibodies against polypeptides, page 7, lines 12-13; preparation of monoclonal antibodies, page 7, lines 26-30; other methods of generating antibodies and

antibody fragments page 8, lines 1-26; methods for conjugating effectors to antibodies, page 11, lines 12-15; methods for attaching antibodies to PEG moieties, page 12, lines 10, 17-23, 28-29; methods for attaching PEG to fragments, page 13, lines 20-32. However, contrary to Applicants arguments, the issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applicants arguments that the standard is that of making an anti-IL-17 antibody and testing to see if it retains the desired biological activity (in this case, for the ability to treat MS) is a position that has been routinely dismissed by the courts, as shown by the decisions cited above.

Further, the instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing an anti-IL-17 antibody other than AB#13 mIgG1. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a

practitioner which would involve the determination of which desired antibodies could be used in the claimed method of treatment. It is this additional of all the potential antibodies which meets the functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein issues are concerned. These decisions have been relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments in the instantly claimed method is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims. In the instant case it is highly improbable that all anti-IL17 antibodies will perform in the manner disclosed and the instant specification does not provide the guidance needed to use all the disparate anti-IL-17 antibodies with any reasonable expectation that these antibodies will be successful in the claimed method.

Applicants argue that the instant claims are not directed to anti-IL-17 antibodies and fragments per se but to a method of treating MS by administering the recited therapeutically effective anti-IL-17 antibodies and fragments to patients in need of such treatment. However, contrary to Applicants arguments, the instant claims are enabled only for a method for reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, the novelty of the instant invention lying in the claimed antibody used because other products such as methylprednisolone, interferon beta-1a, glatiramer acetate and natalizumab can be used to treat the various symptoms of MS such as pain. Furthermore, treatment implies reducing all the symptoms of MS and other than reducing the incidence and severity of the relapse phase in multiple sclerosis (MS) comprising administering an effective amount of an antibody to IL-17 to a subject suffering from multiple sclerosis, wherein the antibody administered is Ab#13 mIgG1 antibody, there is not adequate guidance as to the nature of the anti-IL-17 antibodies that may be produced and used, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

Further, Applicants argue that the Chuntharapai et al. reference cited in the Action is illustrative of the state of the art at the time of the invention, the state of the art is more aptly disclosed in the many references cited in the application, the Chuntharapai et al. reference relates to the IL-8 receptor, not IL-17 or the IL-17 receptor, and that the IL-8 receptor discussed in the Chuntharapai et al. reference is a very different protein and much more difficult to obtain antibodies to than the soluble cytokine IL-17. However, contrary to Applicants arguments, the

Chuntharapai et al. reference has been cited as a generic reference for the premise that blocking activities of monoclonals when compared show disparate blocking on ligand binding and inhibition of ligand binding or no inhibition at all (see page 24, last 2 lines; page 25). It is suggested that by employing conventional claim language, the claims be amended to include the specific antibody supported by the instant specification in the claimed method.

Claim rejections-35 U.S.C. 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10-11, 14-16, 19, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10, line 1, recites the limitation "the treatment". There is insufficient antecedent basis for this limitation in the claim.

Claims 11, 14-15, 17, are rejected as vague and indefinite insofar as they depend on the above rejected claim for their limitations.

Conclusion

No claim is allowed.

Claims 10-11, 14-16, and 19, are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Primary Examiner
Art Unit 1646